

Docket No. VTN 570

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: David C. Turner

Serial No.:10/029,526

Group Art Unit: 1615

Filed: December 21, 2001

Examiner: FUBARA, Blessing

Title: ANTIMICROBIAL LENSES AND METHODS OF THEIR USE

ATTENTION: BOARD OF PATENT APPEALS AND INTERFERENCES



APPELLANTS' BRIEF (37 C.F.R. 1.192)

This is an appeal from the final rejection mailed November 4, 2004, a Notice of Appeal having been mailed on February 3, 2005.

The fees required under Section 1.17(f), and any required petition for extension of time for filing this brief and fees therefor, are addressed within the accompanying TRANSMITTAL OF APPEAL BRIEF.

This brief is transmitted in triplicate. (37 CFR 1.192(a))

This brief contains these items under the following headings, and in the order set forth below (37 CFR 1.192(c)):

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1. REAL PARTY INTEREST

The real party in interest of the subject patent application is Johnson & Johnson Vision Care, Inc, having a principal place of business at 7500 Centurion Parkway, Suite 100, Jacksonville FL 32256.

2. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences pending.

3. STATUS OF CLAIMS

Claims 1-25 are pending. Claims 26 through 52 have been withdrawn.

Claims 1-25 stand rejected as unpatentable under 35 U.S.C. 103 over EP 1,050,314 (Barry, et al.) in view of US 5,515,117 (Dziabo, et al).

4. STATUS OF AMENDMENTS

There have been no amendments to the claims.

5. SUMMARY OF INVENTION

The present invention as recited in the pending claims is related to an antimicrobial lens comprising a coated zeolite. Claim 2 further requires that the zeolite be coated with at least one silane. Claims 3 through 25 depend directly or indirectly from claim 2.

6. STATEMENT OF ISSUES

Whether claims 1 -25 are patentable under 35 U.S.C. 103 over EP 1,050,314 (Barry, et al.) in view of US 5,515,117 (Dziabo, et al).

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7. GROUPING OF CLAIMS

For the purpose of the appeal, the claims stand or fall together.

8. ARGUMENTS

Claims 1-25 are patentable under 35 U.S.C. 103 over EP 1,050,314 (Barry, et al.) in view of US 5,515,117 (Dziabo, et al).

Claim 1 of the present invention recites "an antimicrobial lens comprising a coated zeolite." Claim 3 further recites that the "coated zeolite comprises silver". The present application defines coated zeolites as "zeolites that are treated with hydrophobic substances that slow the release of the antimicrobial metal". See page 4, lines 8-9 of the present specification.

Barry et al. discloses contact lenses which contain ceramic carriers, such as zeolites which retain antimicrobial metal ions. The zeolites may be coated onto a preformed contact lens or incorporated into the lens precursor prior to polymerization. Barry et al. neither discloses nor suggests that the zeolites be treated with hydrophobic substances that slow the release of the antimicrobial metal.

Dziabo et al. discloses covalently bonding a reactable compound to the surface of a preformed contact lens. The reactable coating has a functional portion which covalently bonds to the contact lens and an active portion which provides antimicrobial activity. The active portions disclosed by Dziabo et al. are organic groups. The lenses of Dziabo et al. contain neither zeolites nor silver. Dziabo et al. also does not suggest that the antimicrobial component be treated with hydrophobic substances that slow the release of the antimicrobial metal. In fact, Dziabo, et al. discloses at column 3, lines 65-66 that the antimicrobial component is "substantially silver free".

Examiner has stated at page 3 of the November 4, 2004 final rejection "The polymeric material in Dziabo is a silane and the silane contains or coats antimicrobial agent." Applicants respectfully disagree. The polymeric material disclosed in Dziabo is the polymeric material used

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to form the contact lens. See, column 4, lines 13-15 of Dziabo, et al. It is the functional portion of the reactable component of the antimicrobial component that may be an organosilane group. See column 4, lines 54-67. Accordingly, Dziabo et al. discloses that the antimicrobial component may contain silane. There is nothing in Dziabo et al. which discloses or suggests that the antimicrobial component could be coated with a silane, or any other material to "slow the release of the antimicrobial metal" as is recited in the present claims. Neither Dziabo et al., nor Barry et al. taken alone or in combination disclose or suggest "zeolites that are treated with hydrophobic substances that slow the release of the antimicrobial metal".

In order to maintain a *prime facie* case of obviousness the references themselves must contain some suggestion to make the combination suggested by the Examiner. "[T]here should be something in the prior art or a convincing line of reasoning in the answer suggesting the desirability of combining the reference in such a manner as to arrive at the claimed invention." Ex parte Hiyamizu, 10 U.S.P.Q.2d 1393, 1394 (BPAI 1988). See also, In re Gordon, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984) ("There mere fact that the prior art could be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification.") Applicants respectfully submit that the references fail to suggest zeolites that are treated with hydrophobic substances that slow the release of the antimicrobial metal.

Assuming that a *prima facie* case had been made (which it has not), the present application contains a showing of surprising results sufficient to over it. Table 3 on page 31 compares the release assay results for contact lenses comprising uncoated zeolites (Lens C) and two coated zeolites (Lenses G and H). The table is reproduced below.

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Table 3

	Lens G ¹	Lens H ¹	Lens C ¹
Time			
Days	Ag%	Ag%	Ag%
0	100	100	100
1	48.9	39.4	41
2	29.3	32.9	13
3	30.1	28.8	10
4	31.8	31.8	<9
5	27.9		<9

As is clearly seen from the Table, Lenses G and H retained about three times more silver on day 3 and after than the uncoated lens C. There is absolutely nothing in either Barry et al. or Dziabo et al. which suggests this very substantial improvement in the release rate of silver could be achieved by using a zeolite treated with hydrophobic substances that slow the release of the antimicrobial metal, as is claimed in the present claims.

Reversal of the rejections is respectfully requested.

8.5 CONCLUSION

For the foregoing reasons, the reversal of the rejections relating to claims 6 through 15 are respectfully requested.

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9. APPENDIX OF CLAIMS INVOLVED IN THE APPEAL

(See attached)

Respectfully submitted,

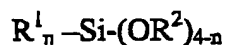
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APPENDIX OF CLAIMS INVOLVED IN THE APPEAL

1. An antimicrobial lens comprising a coated zeolite.
2. The antimicrobial lens of claim 1, wherein the zeolite is coated with a composition comprising at least one silane.
3. The lens of claim 2 wherein the coated zeolite comprises silver.
4. The lens of claim 2 wherein the lens is a contact lens.
5. The lens of claim 2 wherein the silane comprises a composition of Formula I.



I

wherein

R¹ is C₁₋₂₀alkyl, C₁₋₈alkenyl, phenyl, phenylC₁₋₈alkyl, haloC₁₋₈alkyl, fluoroC₁₋₈alkyl, C₁₋₈alkoxycarbonylC₁₋₈alkyl, or C₁₋₈alkylsiloxyl;

R² is C₁₋₆alkyl, C₁₋₈alkenyl phenyl, phenylC₁₋₈alkyl, haloC₁₋₈alkyl, or C₁₋₈alkoxycarbonylC₁₋₈alkyl; and

n is 1-3.

6. The lens of claim 5 wherein R¹ is C₁₀alkyl.

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7. The lens of claim 5 wherein R^1 is C_{18} alkyl.

8. The lens of claim 5 wherein R^1 is C_8 alkyl.

9. The lens of claim 5 wherein R^2 is C_{1-3} alkyl.

10. The lens of claim 2 wherein, the silane comprises a composition of Formula II



II

wherein

R^1 is C_{1-20} alkyl, C_{1-8} alkenyl, phenyl, phenyl C_{1-8} alkyl, halo C_{1-8} alkyl, fluoro C_{1-8} alkyl, C_{1-8} alkoxycarbonyl C_{1-8} alkyl, or C_{1-8} alkylsiloxyl;

X is any group that can be displaced with a nucleophile; and

n is 1-3.

11. The lens of claim 10 wherein X is selected from the group consisting of is chloro, bromo, iodo, acyloxy, hydroxyl, and $NH-Si(CH_3)_3$.

12. The lens of claim 10 wherein R^1 is C_{10} alkyl.

13. The lens of claim 10 wherein X is acyloxy or chloro.

14. The lens of claim 10 wherein R^1 is C_{18} alkyl.

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15. The lens of claim 2 wherein the silane is selected from the group consisting of phenyltrimethoxysilane, phenyltriethoxysilane, diphenyldimethoxysilane, diphenyldiethoxysilane, methyltrimethoxysilane, methyltriethoxysilane, methyltripropoxysilane, ethyltrimethoxysilane, ethyltriethoxysilane, ethyltripropoxysilane, propyltrimethoxysilane, propyltriethoxysilane, propyltripropoxysilane, butyltrimethoxysilane, butyltriethoxysilane, hexyltrimethoxysilane, hexyltriethoxysilane, benzyltrimethoxysilane, octyltrimethoxysilane, octyltriethoxysilane, octyltripropoxysilane, decyltrimethoxysilane, dodecyltrimethoxysilane, octadecyltrimethoxysilane, tetradecyltrimethoxysilane, tetradecyltriethoxysilane, hexadecyltrimethoxysilane, hexadecyltriethoxysilane, dimethyldimethoxysilane, dimethyldiethoxysilane, dibutyldimethoxysilane, octadecylmethyldimethoxysilane, octadecyldimethylmethoxysilane, acetoxypentyltrimethoxysilane, octadecyltrichlorosilane, trifluoropentyltrimethoxysilane, perfluorodecyl- 1H,1H,2H,2H-dimethylchlorosilane, N-(2-aminoethyl)-3-aminopentyltrimethoxysilane, and 3-aminopentyltrimethoxysilane.
16. The lens of claim 2 wherein the silane is selected from the group consisting of octadecyltrimethoxy silane, octyltrimethoxysilane, butyltrimethoxysilane, octadecyltrichlorosilane, and acetoxypentyltrimethoxysilane.
17. The lens of claim 2 wherein the silane is octyldecyltrimethoxysilane.
18. The lens of claim 2 having
more than about 0.02 weight percent coated zeolite, and
less about 1.0 weight percent coated zeolite.
19. The lens of claim 2 having

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more than about 0.025 weight percent coated zeolite, and
less about 0.1 weight percent coated zeolite.

20. The lens of claim 2 having

more than about zero weight percent coated zeolite, and
less than about 0.1 weight percent coated zeolite.

21. The lens of claim 17 having

more than about zero weight percent coated zeolite, and
less than about 0.1 weight percent coated zeolite.

22. The lens of claim 17 wherein the coated zeolite comprises silver.

23. The lens of claim 2 wherein the coated zeolites comprise at least two different compositions of Formula I.

24. The lens of claim 2 wherein the coated zeolites comprise at two different compositions of Formula II.

25. The lens of claim 2 wherein the coated zeolites comprise at least one compositions of Formula I, at least one composition of Formula II or mixtures thereof.

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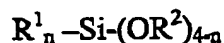
/Karen A. Harding/
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APPENDIX OF CLAIMS INVOLVED IN THE APPEAL

1. An antimicrobial lens comprising a coated zeolite.
2. The antimicrobial lens of claim 1, wherein the zeolite is coated with a composition comprising at least one silane.
3. The lens of claim 2 wherein the coated zeolite comprises silver.
4. The lens of claim 2 wherein the lens is a contact lens.
5. The lens of claim 2 wherein the silane comprises a composition of Formula I.



I

wherein

R^1 is C_{1-20} alkyl, C_{1-8} alkenyl, phenyl, phenyl C_{1-8} alkyl, halo C_{1-8} alkyl, fluoro C_{1-8} alkyl, C_{1-8} alkoxycarbonyl C_{1-8} alkyl, or C_{1-8} alkylsiloxyl;

R^2 is C_{1-8} alkyl, C_{1-8} alkenyl phenyl, phenyl C_{1-8} alkyl, halo C_{1-8} alkyl, or C_{1-8} alkoxycarbonyl C_{1-8} alkyl; and

n is 1-3.

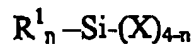
6. The lens of claim 5 wherein R^1 is C_{10} alkyl.

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7. The lens of claim 5 wherein R^1 is C_{18} alkyl.
8. The lens of claim 5 wherein R^1 is C_8 alkyl.
9. The lens of claim 5 wherein R^2 is C_{1-3} alkyl.
10. The lens of claim 2 wherein, the silane comprises a composition of Formula II


$$II$$

wherein

R^1 is C_{1-20} alkyl, C_{1-8} alkenyl, phenyl, phenyl C_{1-8} alkyl, halo C_{1-8} alkyl, fluoro C_{1-8} alkyl, C_{1-8} alkoxycarbonyl C_{1-8} alkyl, or C_{1-8} alkylsiloxyl;

X is any group that can be displaced with a nucleophile; and

n is 1-3.

11. The lens of claim 10 wherein X is selected from the group consisting of is chloro, bromo, iodo, acyloxy, hydroxyl, and $NH-Si(CH_3)_3$.
12. The lens of claim 10 wherein R^1 is C_{10} alkyl.
13. The lens of claim 10 wherein X is acyloxy or chloro.
14. The lens of claim 10 wherein R^1 is C_{18} alkyl.

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15. The lens of claim 2 wherein the silane is selected from the group consisting of phenyltrimethoxysilane, phenyltriethoxysilane, diphenyldimethoxysilane, diphenyldiethoxysilane, methyltrimethoxysilane, methyltriethoxysilane, methyltripropoxysilane, ethyltrimethoxysilane, ethyltriethoxysilane, ethyltripropoxysilane, propyltrimethoxysilane, propyltriethoxysilane, propyltripropoxysilane, butyltrimethoxysilane, butyltriethoxysilane, hexyltrimethoxysilane, hexyltriethoxysilane, benzyltrimethoxysilane, octyltrimethoxysilane, octyltriethoxysilane, octyltripropoxysilane, decyltrimethoxysilane, dodecyltrimethoxysilane, octadecyltrimethoxysilane, tetradecyltrimethoxysilane, tetradecyltriethoxysilane, hexadecyltrimethoxysilane, hexadecyltriethoxysilane, dimethyldimethoxysilane, dimethyldiethoxysilane, dibutyldimethoxysilane, octadecylmethyldimethoxysilane, octadecyldimethylmethoxysilane, acetoxypentyltrimethoxysilane, octadecyltrichlorosilane, trifluoropentyltrimethoxysilane, perfluorodecyl- 1H,1H,2H,2H-dimethylchlorosilane, N-(2-aminoethyl)-3-aminopentyltrimethoxysilane, and 3-aminopentyltrimethoxysilane.
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less about 0.1 weight percent coated zeolite.

20. The lens of claim 2 having

more than about zero weight percent coated zeolite, and
less than about 0.1 weight percent coated zeolite.

21. The lens of claim 17 having

more than about zero weight percent coated zeolite, and
less than about 0.1 weight percent coated zeolite.

22. The lens of claim 17 wherein the coated zeolite comprises silver.

23. The lens of claim 2 wherein the coated zeolites comprise at least two different compositions of Formula I.

24. The lens of claim 2 wherein the coated zeolites comprise at two different compositions of Formula II.

25. The lens of claim 2 wherein the coated zeolites comprise at least one compositions of Formula I, at least one composition of Formula II or mixtures thereof.